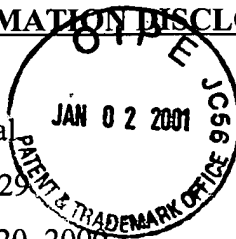


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

APPLICANT: Mark et al. DOCKET NO.: 112701-006  
 SERIAL NO: 09/622,629 ART UNIT: 1761  
 FILED: October 20, 2000 EXAMINER: Unknown  
 INVENTION: "CALORICALLY DENSE NUTRITIONAL COMPOSITION"



RECEIVED  
 JAN 16 2001  
 TECH CENTER 1600/2900

Assistant Commissioner for Patents

Washington, D.C. 20231

S I R:

In accordance with the provisions of 37 C.F.R. 1.56, Applicants request that citation and examination of the references identified below and on the attached PTO-1449 form, copies of which can be found in the priority application Serial No. 09/025,363, filed February 18, 1998, be made during the course of examination of the above-mentioned application for United States Patent.

U.S. PATENTS

<u>Patent Number</u>	<u>Inventor</u>	<u>Publication Date</u>
4,112,123	Roberts	September 5, 1978
4,358,465	Brule et al.	November 9, 1982
4,361,587	Brule et al.	November 20, 1982
4,427,658	Maubois et al.	January 24, 1984
4,495,176	Brule et al.	January 22, 1985
4,670,268	Mahmoud	June 20, 1987
4,740,462	Brule et al.	April 26, 1988
4,753,963	Jandacek et al.	June 28, 1988
4,816,398	Brule et al.	March 28, 1989
4,920,098	Cotter et al.	April 24, 1990
4,931,300	Monte	June 5, 1990

RECEIVED  
 JAN 10 2001  
 TC 1700 MAIL ROOM

4,980,450	Brule et al.	December 25, 1990
5,028,589	Brule et al.	July 2, 1991
5,053,387	Alexander	October 1, 1991
5,055,446	Alexander et al.	October 8, 1991
5,156,875	Monte	October 20, 1992
5,166,189	Trimbo et al.	November 24, 1992
5,221,668	Henningfield et al.	June 22, 1993
5,223,285	DeMichele et al.	June 29, 1993
5,260,279	Greenberg	November 9, 1993
5,340,603	Neylan et al.	August 23, 1994
5,422,127	Dube et al.	June 6, 1995
5,438,042	Schmidl et al.	August 1, 1995
5,480,872	Cope et al.	January 2, 1996
5,504,072	Schmidl et al.	April 2, 1996
5,547,927	Cope et al.	August 20, 1996
5,549,905	Mark et al.	August 27, 1996
5,574,065	Trimbo	November 12, 1996
5,589,468	Lin et al.	December 31, 1996
5,661,123	Stalker et al.	August 26, 1997
5,635,199	Trimbo	December 23, 1997
5,700,782	Cope et al.	December 23, 1997
5,714,472	Gray et al.	February 3, 1998
5,723,446	Gray et al.	March 3, 1998
5,733,884	Barbul et al.	March 31, 1998
5,766,621	Trimbo et al.	June 16, 1998

#### **FOREIGN PATENTS**

<u>Patent Number</u>	<u>Country</u>	<u>Publication Date</u>
0 189 160	Europe	July 30, 1986
EP 0 721 742 A1	Europe	July 17, 1996
97/16079	PCT	May 9, 1997

### OTHER DOCUMENTS

- Alexander et al., "Beneficial Effects of Aggressive Protein Feeding in Severely Burned Children", *Ann. Surg.*, Vol. 192, No. 4, 1980, pp. 505-517.
- Anderson et al., "Intestinal Protein Loss During Enteral Alimentation in Critically Ill Patients", *J Parenter Enteral Nutr.*, Vol. 14 (Suppl), No. 1, 1990, pg. 24, Abstract.
- August et al., "Determination of Zinc and Copper Absorption at Three Dietary Zn-Cu Ratios by Using Stable Isotope Methods in Young Adult and Elderly Subjects", *Am J Clin Nutr*, Vol. 50, 1989, pp. 1457-1463.
- Austin, "Water: Guidelines for Nutritional Support", *Nutritional Support Services*, Vol. 6, No. 9, 1986, pp. 27-29.
- Belcher et al., "Determinants of Urinary Nitrogen Excretion in Burned Patients", *Burns*, Vol. 14, No. 4, 1988, pp. 303-307.
- Bell et al., "Alternative lipid sources for enteral and parenteral nutrition: Long- and medium-chain triglycerides, structured triglycerides, and fish oils", *Journal of the American Dietetic Association*, Vol. 91, No. 1, 1991, pp. 74-78.
- Bjerve et al., "Alpha-Linolenic Acid Deficiency in Patients on Long-Term Gastric-Tube Feeding: Estimation of Linolenic Acid and Long-Chain Unsaturated n-3 Fatty Acid Requirement in Man", *Am J Clin Nutr*, Vol. 5, 1987, pp. 66-77.
- Bjerve et al., "Alpha-linolenic acid deficiency in man: effect of ethyl linolenate on plasma and erythrocyte fatty acid composition and biosynthesis of prostanoids", *Am J Clin Nutr*, Vol. 46, 1987, pp. 570-576.
- Bogden et al., "Zinc and Immunocompetence in Elderly People: Effects of Zinc Supplementation for 3 Months", *Am J Clin Nutr*, Vol. 48, 1988, pp. 655-663.
- Bogden et al., "Zinc and Immunocompetence in the Elderly: Baseline Data on Zinc Nutriture and Immunity in Unsupplemented Subjects", *Am J Clin Nutr*, Vol. 46, 1987, pp. 101- 109.
- Borum, "Role of Carnitine in Lipid Metabolism", *Lipids in Modern Nutrition*, New York: Raven Press, 1987, pp. 51-58.
- Borum et al., "Carnitine content of liquid formulas and special diets", *Am J Clin Nutr*, Vol. 32, 1979, pp. 2272-2276.
- Breslow, "Nutritional Status and Dietary Intake of Patients With Pressure Ulcers: Review of Research Literature 1943 to 1989", *Decubitus*, Vol. 4, No. 1, 1991, pp. 16-21.

- Brinson, "The Effect of Peptide-Based Diets on the Intestinal Microcirculation in a Rat Model", *Nutr Clin Prac*, Vol. 5, 1990, pp. 238-240.
- Brinson et al., "Diarrhea Associated With Severe Hypoalbuminemia: A Comparison of a Peptide-Based Chemically Defined Diet and Standard Enteral Alimentation", *Critical Care Medicine*, Vol. 16, No. 2, 1988, pp. 130-136.
- Brinson et al., "Intestinal Absorption of Peptide Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats: A Paired Analysis", *Critical Care Medicine*, Vol. 17, No. 7, 1989, pp. 657-660.
- Bynoe et al., "Nutrition Support in Trauma Patients", *Nutr Clin Prac*, Vol. 4, 1988, pp. 137-144.
- Cerra et al., "Enteral Nutrition in Hypermetabolic Surgical Patients", *Critical Care Medicine*, Vol. 17, No. 7, 1989, pp. 619-622.
- Cerra et al., "The Effect of Stress Level, Amino Acid Formula, and Nitrogen Dose on Nitrogen Retention in Traumatic and Septic Stress", *Ann. Surg.*, Vol. 205, No. 3, 1987, pp. 282-287.
- Cerra et al., "What's New in Nutrition Support in Critical Care", *Perspective in Clinical Nutrition*, Kinney, Borum (Eds.), Urban & Schwarzenberg: Baltimore-Munich, 1989, pp. 323-338.
- Chandra, "Trace Element Regulation of Immunity and Infection", *Journal of the American College of Nutrition*, Vol. 4, No. 1, 1985, pp. 5-16.
- Chernoff et al., "The effect of a very high-protein liquid formula (Replete®) on decubitus ulcer healing in long-term tube-fed institutionalized patients", *J Am Diet Assoc.*, Vol. 90, 1991.
- Clintec Nutrition Company, *Proper Nutrition For ICU Patients Is Critical*, Brochure, 1994.
- Clintec Nutrition Company, *When You Create Such A Unique Enteral Formula, It's Hard Not To Create Attention*, Brochure, 1994.
- Clintec Nutrition Company, *Crucial Needs Require A Curcial™ Solution*, Brochure, 1994.
- Clintec Nutrition Company, *Crucial™ Compared To Perative®*, Brochure, 1995.
- Clintec Nutrition Company, *When Your First Choice Has To Be Your Best Choice*, Reabilan® Brochure (Undated).
- Clintec Nutrition Company, *Reabilan HN*, Brochure (Undated).
- D'Atellis et al., "Branched-Chain Amino Acids", *Nutrition in Critical Care*, In Zaloga (ed.), St. Louis, MO: Mosby, 1994, pp. 81-106.

- Dominioni et al., "Enteral Feeding in Burn Hypermetabolism: Nutritional and Metabolic Effects of Different Levels of Calorie and Protein Intake", *Journal of Parenteral and Enteral Nutrition*, Vol. 9, No. 3, 1985, pp. 269-279.
- Dominioni et al., "Prevention of Severe Postburn Hypermetabolism and Catabolism by Immediate Intragastric Feeding", *J. Burn Care Rehab.*, Vol. 5, No. 2, 1984, pp. 106-112.
- Ehrlich et al., "Effects of Cortisone and Vitamin A on Wound Healing", *Annals of Surgery*, Vol. 167, No. 3, 1968, pp. 324-328.
- Ehrlich et al., "Effects of Vitamin A and Glucocorticoids upon Inflammation and Collagen Synthesis", *Ann. Surg.*, Vol. 177, No. 2, 1973, pp. 222-227.
- Ehrlich et al., "Effects of Beta-Carotene, Vitamin A, and Glucocorticoids on Collagen Synthesis in Wounds", *Proc. Soc. Exp Biol Med.*, Vol. 137, No. 1, 1971, pp. 936-938.
- Fabiani et al., "Oral Hyperalimentation in the Nutritional Management of Burned Patients", *SAMJ*, Vol. 67, 1985, pp. 768-770.
- Freeman et al., "Effects of Magnesium Infusions on Magnesium and Nitrogen Balance During Parenteral Nutrition", *The Canadian Journal of Surgery*, Vol. 25, No. 5, 1982, pp. 570-574.
- Gegge et al., "Nutritional Requirement for Taurine in Patients Receiving Long-Term Parenteral Nutrition", *The New England Journal of Medicine*, Vol. 312, No. 3, 1985, pp. 142-146.
- Goodson et al., "Wound Healing", *Nutrition and Metabolism in Patient Care*, In: Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, 635-642.
- Gottschlich et al., "Enteral Nutrition in Patients with Burns or Trauma", *Clinical Nutrition Enteral and Tube Feeding 2nd Edition*, In: Rombeau et al. (Eds.), Philadelphia, PA: WB Saunders, 1990, pp. 306-324.
- Gottschlich et al., "Vitamin Supplementation in the Patient with Burns", *J. Burn Care Rehab.*, Vol. 11, No. 3, 1990, pp. 275-279.
- Granger et al., "Intestinal Absorption of Elemental and Standard Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats", *Journal of Parenteral and Enteral Nutrition*, Vol. 12, No. 3, 1988, pp. 278-281.
- Greenberger et al., "Medium-Chain Triglycerides: Physiologic Considerations and Clinical Implications", *The New England Journal of Medicine*, Vol. 280, No. 19, 1969, pp. 1045-1058.
- Hadley et al., "Nutrition and Wound Healing", *Top Clin. Nutr.*, Vol. 5, No. 4, 1990, pp. 72-81.

- Hallbook et al, "Serum-Zinc and Healing of Venous Leg Ulcers", *Lancet*, 1972, pp. 780- 782.
- Hayes, "Vitamin-Like Molecules (D) Taurine", *Modern Nutrition in Health and Disease, 7th Edition*, Philadelphia: Lea and Febiger, 1988, pp. 464-470.
- Heymsfield et al., "Respiratory, cardiovascular, and metabolic effects of enteral hyperalimentation: influence of formula dose and composition", *The American Journal of Clinical Nutrition*, Vol. 40, 1984, pp. 116-130.
- Holman, "Function and Biologic Activities of Essential Fatty Acids in Man", *Fat Emulsion in Parenteral Nutrition*, Chicago: American Medical Association, 1976, pp. 5-14.
- Holt, "Medium Chain Triglycerides: A Useful Adjunct in Nutritional Therapy", *Gastroenterology*, Vol. 53, No. 6, 1967, pp. 961-966.
- Hunt, "Control of Wound Healing With Cortisone and Vitamin A", *The Ultrastructure of Collagen*, In: Longacre JJ (ed.), Springfield, IL: Charles C. Thomas, 1976, pp. 497-508.
- Hunt et al., "Effect of Vitamin A on Reversing the Inhibitory Effect of Cortisone on Healing of Open Wounds in Animals and Man", *Annals of Surgery*, Vol. 170, No. 4, 1969, pp. 633-641.
- Hunt et al., "Selenium Depletion in Burn Patients", *Journal of Parenteral and Enteral Nutrition*, Vol. 8, No. 6, 1984, pp. 695-699.
- Ireton-Jones et al., "Nutrition for Adult Burn Patients: A Review", *Nutr. Clin Prac.*, Vol. 6, No. 1, 1991, pp. 3-7.
- Jahoor et al., "Dynamics of the Protein Metabolic Response to Burn Injury", *Metabolism*, Vol. 37, No. 4, 1988, pp. 330-337.
- Johnson et al., "Metabolism of Medium-Chain Triglyceride Lipid Emulsion", *Nutrition International*, Vol. 2, No. 3, 1986, pp. 150-158.
- Joint FAO/WHO Ad Hoc Expert Committee, "Protein and Energy Requirements: a joint FAO/WHO Memorandum," *Bulletin of the World Health Organization*, Vol. 57, 1979, pp. 65-79.
- Kaunitz, "Clinical uses of medium-chain triglycerides", *Drug Therapy*, Vol. 8, 1978, pp. 91-96.
- Kissileff et al., "Physiology of the Control of Food Intake", *Ann. Rev. Nutr.*, Vol. 2, 1982, pp. 371-418.
- Kubo et al., "Fluid and Electrolyte Problems of Tube-Fed Patients", *American Journal of Nursing*, Vol. 76, No. 6, 1976, pp. 912-916.

- Law et al., "The Effect of Dietary Protein Depletion on Immunocompetence: The Importance of Nutritional Repletion Prior to Immunologic Induction", *Ann. Surg.*, Vol. 179, No. 2, 1974, pp. 168-173.
- Levenson, "Micronutrients (Vitamins, Trace Minerals)", In ASPEN Program Manual of Proceedings of The 16th Clinical Congress, 1992, pp. 189-198.
- Long et al., "Metabolic Response to Injury and Illness: Estimation of Energy and Protein Needs from Indirect Calorimetry and Nitrogen Balance", *Journal of Parenteral and Enteral Nutrition*, Vol. 3, No. 6, 1979, pp. 452-456.
- Mahan et al., "The Assessment of Nutritional Status", *Krause's Food and Nutrition & Diet Therapy, 8th Edition*, Philadelphia: W.B. Saunders Company, 1992, pp. 293-313.
- Mandt et al., "Nutritional Requirements", *Nutrition Support Handbook*, In: Teasley- Strausberg (ed.), Cincinnati, OH: Harvey Whitney Books Co., 1992, pp. 19-36.
- Mascioli et al., "Intravenous Infusion of a Physical Mixture of Medium and Long Chain Triglyceride Emulsion", *Clin. Res.*, Vol. 33, 1985, 275A.
- McClave et al., "Immunonutrition and Enteral Hyperalimentation of Critically Ill Patients", *Digestive Diseases and Sciences*, Vol. 37, No. 8, 1992, pp. 1153-1161.
- Mead Johnson, *Enteral Nutritionals Product Handbook*, bearing Nos. A2688-2693.
- Mead Johnson Enteral Nutritionals Brochure bearing Nos. B00083.
- Mead Johnson Brochure bearing Nos. B00322-B00323.
- Mead Johnson, *Metabolic and Nutrition Support for Trauma and Burn Patients A Symposium*, Abstracts, 1982, pp. 1-13.
- Meredith et al., "Visceral Protein Levels in Trauma Patients Are Greater with Peptide Diet Than with Intact Protein Diet", *The Journal of Trauma*, Vol. 30, No. 7, 1990, pp. 825-829.
- National Research Council, "Recommended Dietary Allowances, 10th Edition," Washington, D.C.: National Academy Press 1989.
- Nichols et al., "Magnesium supplementation in protein-calorie malnutrition", *The American Journal of Clinical Nutrition*, Vol. 31, 1978, pp. 176-188.
- Nutritional Care of Metabolically Stressed Patients*, Proceedings from the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium, White Sulphur Springs, West Virginia, 1983, pp. 1-77.

Ortiz et al., "A Comparative Post-Operative Study - An Enteral Solution Based on Free Amino Acids, *Gastroenterologic Clinique et Biologique*, Vol. 9, No. 2, 1985, pp. 182-183.

Pearson et al., "An Estimation of the Potassium Requirements For Equilibrium in Burned Patients", *Surgery Gynecology & Obstetrics*, Vol. 112, No. 3, 1961, pp. 263-273.

Pories et al., "Acceleration of Wound Healing in Man With Zinc Sulphate Given By Mouth", *Lancet*, 1967, pp121-124.

Prasad et al., "Serum Thymulin in Human Zinc Deficiency", *J. Clin. Invest.*, Vol. 82, 1988, pp. 1202-1210.

*Principles of Nutritional Support: Proceedings From the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium*, White Sulphur Springs, West Virginia, 1982, pp. 1-25.

Randall et al., "Randomized Clinical Trial in Hospitalized Patients Using Intravenous Medium Chain Triglyceride Emulsions", *Clin. Res.*, Vol. 33, 1985, 276A.

Ringsdorf et al., "Vitamin C and Human Wound Healing", *Oral Surgery*, Vol. 53, No. 3, 1982, pp. 231-236.

Ross et al., "Wound Healing and Collagen Formation - II. Fine Structure in Experimental Scurvy", *The Journal of Cell Biology*, Vol. 12, 1962, pp. 533-551.

Ross et al., "Wound Healing and Collagen Formation - V. Quantitative Electron Microscope Radioautographic Observations of Proline-H<sup>3</sup> Utilization by Fibroblasts", *The Journal of Cell Biology*, Vol. 27, 1965, pp. 83-106.

Ross et al., "Vitamin A as a Hormone: Recent Advances in Understanding the Actions of Retinol, Retinoic Acid, and Beta Carotene", *Journal of The American Dietetic Association*, Vol. 93, No. 11, 1993, pp. 1285-1290.

Ross Laboratories Brochure, *Specialized Elemental Nutrition With Glutamine - The Role of ALITRAQ™ Specialized Elemental Nutrition With Glutamine*, 1991.

Ross Laboratories Brochure, *Introducing ALITRAQ™ Specialized Elemental Nutrition With Glutamine*, 1992.

Ross Laboratories Brochure, *Introducing PERATIVE™*, 1992.

Sailer et al., "Medium Chain Triglycerides in Parenteral Nutrition" *Journal of Parenteral and Enteral Nutrition*, Vol. 5, No. 2, 1981, pp. 115-119.

Sandoz Nutrition Brochure, *IMPACT®*, 1993.



Sandoz Nutrition Brochure, *INTRODUCING IMPACT®*, 1989.

Sandoz Nutrition Brochure, *IMPACT®*, 1991.

Sandstead et al., "Zinc and Wound Healing: Effects of Zinc Deficiency and Zinc Supplementation", *The American Journal of Clinical Nutrition*, Vol. 23, No. 5, 1970, pp. 514-519.

Silk, "Nutritional Support in Hospital Practice", Oxford, Blackwell Scientific Publications, 1983, pp. 79-82.

Simopoulos, "Omega-3 fatty acids in health and disease and in growth and development", *Am J Clin Nutr*, Vol. 54, 1991, pp. 438-63.

Spiller et al., "Malabsorption", *Nutrition and Metabolism in Patient Care*, Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, pp. 281-304.

Stotts et al., "Nutrition: A Critical Component of Wound Healing", *AACN Clin Issues*, Vol. 1, No. 3, 1990, pp. 585-594.

Sturman et al., "The Biology of Taurine in Nutrition and Development", *Adv. Nutr Res*, Vol. 3, 1980, pp. 231-299.

Sucher, "Medium Chain Triglycerides: A Review of Their Enteral Use in Clinical Nutrition", *Nutrition in Clinical Practice*, 1986, pp. 146-150.

*Symposium Highlights Metabolic and Nutrition Support for Trauma and Burn Patients*, White Sulphur Springs, West Virginia, 1982, pp. 1-26.

Szebeni et al., "Vitamin A Levels in the Serum of Burned Patients", *Burns*, Vol. 7, No. 5, 1981, pp. 313-318.

TraumaCal, *Feeding the Hypermetabolic Patient, Clinical Experience, A Symposium*, 1983, pp. 1-74.

TraumaCal Product Cards bearing Nos. B000001-10.

TraumaCal Documents bearing Nos. B00088-105.

TraumaCal Document bearing No. B00181.

TraumaCal Document bearing Nos. B00261-265.

TraumaCal Document bearing No. B00293.

TraumaCal Document bearing Nos. B00384-385.

TraumaCal Label bearing No. B00441.

TraumaCal Brochure bearing Nos. B00567-570.

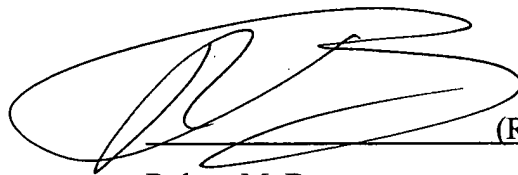
Twyman et al., "High Protein Enteral Feedings: A Means of Achieving Positive Nitrogen Balance in Head Injured Patients", *Journal of Parenteral and Enteral Nutrition*, Vol. 9, No. 6, 1985, pp. 679-684.

Waxman et al., "Protein Loss Across Burn Wounds", *The Journal of Trauma*, Vol. 27, No. 2, 1987, pp. 136-140.

Ziegler et al., "Efficiency of Enteral Nitrogen Support in Surgical Patients: Small Peptides v Non-Degraded Proteins", *Gut*, Vol. 31, 1990, pp. 1277-1283.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,



(Reg. No. 30,142)

Robert M. Barrett

BELL, BOYD & LLOYD LLC

P.O. Box 1135

Chicago, Illinois 60690-1135

(312) 807-4204

ATTORNEY FOR APPLICANTS